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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,390	07/09/2003	Harold N. Trick	KSURF-08151	9787
72960	7590	11/12/2008		
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			EXAMINER IBRAHIM, MEDINA AHMED	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 11/12/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,390

Applicant(s)

TRICK ET AL.

Examiner

Medina A. Ibrahim

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-9, 14-23, 26, 29-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 14, 21, 22, 37 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/08 has been entered. The declaration of Harold Trick of 08/06/08 has been considered.

Claims 1, 7-9, 14-23, 26, 29-38, and 40-42 are pending.

Claims 7-8, 14, 21-22, 37, and 41 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are under examination.

The written description rejection under 112, 1st paragraph has been withdrawn in view of Applicant's arguments and the supporting 1.132 Declaration of Harold Trick . The declaration is not persuasive regarding the art rejection as set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Tobias et al (WO 01/37654) and MUSHEGIAN et al (WO 01/96584) in view of Zipperlen et al (The EMBO Journal (2001), vol. 20 (15), pp. 3984-3992).

The claims are drawn to a transgenic plant comprising a nucleic acid sequence encoding an orally active double stranded RNA targeting for genetic inhibition a *Heterodera glycines* embryonic lethal phenotype gene, wherein nematodes ingesting said double stranded nematode RNA do not proliferate; seed from the transgenic plant comprising said nucleic acid sequence; a vector comprising said nucleic acid sequence comprising a sense sequence linked to its complementary antisense sequence operably linked to a plant promoter; said sense and its complementary antisense sequences are separated by a loop sequence and operably linked to separate promoters; said promoter is a tissue-specific or a constitutive promoter; a method for controlling *Heterodera glycines* by providing said transgenic soybean.

Tobias et al teach methods of inhibition of parasitic nematodes in a plant by transforming the plant with DNA sequences encoding a dsRNA that targets a substantially identical endogenous gene or gene portion; said endogenous gene is essential in nematode growth, development, sex determination, and reproduction, e.g. transcription factors, cell cycle regulators, embryo lethal mutants, etc; and that such genes have been isolated from parasitic nematodes *Heterodera* and *Meloidogyne* or can be identified using sequence information from cloned *C. elegans* orthologs known in the prior art (see pages 9-10). Tobias et al also teach that the dsRNA may be at least 25 nucleotides in length and is expressed in feeding cells which is taken up by the parasitic nematode. The cited reference also teaches production of dsRNA in the transgenic plant or root cultures, and analysis of the transgenic plants for resistance against nematodes including *Heterodera glycines*. The cited reference further teaches the generation of plant expression vectors comprising one or more tissue-specific or constitutive promoters for expression of one or more DNA sequences and transformed plants and plant cells expressing dsRNA and having resistance to plant parasitic cyst and root knot nematodes as compared to non-transformed plant/cells. Tobias et al specifically teaches transgenic plants expressing a dsRNA that targets the nematode unc-17 gene encoding vesicular acetylcholine transporter; the reference teaches that if this gene is absent or mutated, proper development of the nematode is stopped (see at least pages 17-18; 20-22; 28-29; 36-39; and claims on pages 40-43). At page 6, the cited reference teaches that soybean cyst (*Heterodera glycines*) and root knot (*Meloidogyne incognita*) nematodes are the major source of economic loss and the

need to use dsRNA technology which have been shown to effectively and safely control other plant pathogens in transgenic plants such as viruses.

MUSHEGIAN et al teach a method of inhibiting nematodes in a plant by transforming the plant with polynucleotide sequences encoding a double stranded RNA or RNAi molecules; said dsRNA comprising sense and antisense polynucleotide sequences which are separated by a linker sequence; the dsRNA comprises a sequence identical to a target gene (or fragment thereof) linked directly or indirectly, to a polynucleotide sequence complementary to the sequence of the target gene (or fragment thereof). Mushegian et al also teach that the dsRNA or RNAi are useful in killing nematodes or inhibiting their growth, development and parasitism by disrupting genes essential for nematode growth, development and parasitism. The target genes for disruption in the nematode include genes encoding proteins involved in ribosome assembly, transport proteins, protein production, folding and processing, production of polynucleotides; the dsRNA is expressed in plant cells including root cells that is taken up by nematodes during feeding to block the function of the target gene (see at least pages 6-7). MUSHEGIAN et al also teach plant expression vectors comprising polynucleotide sequences encoding double stranded RNA or RNAi molecules operably linked to a root-specific promoter, constitutive or nematode inducible promoter and transgenic plant and plant tissue expressing said vectors (see at least pages 27-30; Fig. 8, and claim 141).

While each of Tobias et al and Mushegian et al teach targeting genes essential

for nematode growth/ development and parasitism, they do not explicitly disclose well characterized embryonic lethal genes from nematodes.

Zipperlen et al teach identification of embryonic lethal genes from *C.elegans*.

It would have been obvious to one of ordinary skill in the art to use the method of controlling plant parasitic nematodes by transforming the plant with a dsRNA construct that targets endogenous nematode genes essential for nematode development and growth as taught by each of Tobias et al and Mushegian et al, and to modify that method by incorporating one or more of the embryonic lethal genes taught by Zipperlen et al; said embryonic lethal genes can be identified and obtained from *Heterodera glycines* using sequence information from cloned *C. elegans* orthologs known in the prior art as suggested by Tobias et al, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to use dsRNA technology to control *Heterodera glycines* in a transgenic plant, given that the use dsRNA is more safe and effective as compared to other known methods of controlling nematodes in transgenic plants as suggested by each of Tobias et al and Mushegian et al. Therefore, the invention as whole was a prima facie obvious.

The MPEP 2141 states “[p]rior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations..... The “mere existence of differences between the prior art and an invention does not establish the invention’s nonobviousness.” *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976).

In *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art.” It states “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at ___, 82 USPQ2d at 1395. The Supreme Court further stated that:

“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at ___, 82 USPQ2d at 1396.

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at ___, 82 USPQ2d at 1396.

See also *United States v. Adams*, . . . [t]he Court recognized that when a patent

claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *Id.* at ___, 82 USPQ2d at 1395"; *Ex parte Kubin*, 83 USPQ2d 1410 (*Bd. Pat. App. & Int.*2007); and *Ex parte Smith*...USPQ2d-at 20 (*Bd. Pat. App & Interf.* June 25, 2007) (citing KRS, 82 USPQ2d at 1396)

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
11/10/2008

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638